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**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**[Docket No. DEA-420F]**

**Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2016**

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final Order.

**SUMMARY:** This final order establishes the initial 2016 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

**DATES:** Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, Telephone: (202) 598-6812.

**SUPPLEMENTARY INFORMATION:**

**Legal Authority**

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended.

Titles II and III are referred to as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, and are collectively referred to as the “Controlled Substances Act” or the “CSA” for the purpose of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Section 306 of the Controlled Substances Act (CSA), 21 U.S.C. 826, requires the Attorney General to determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. This responsibility has been delegated to the Administrator of the DEA through 28 CFR 0.100(b).

## **Background**

The 2016 aggregate production quotas and assessment of annual needs represent those quantities of schedule I and II controlled substances and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine that may be manufactured in the United States in 2016 to provide for the estimated medical, scientific, research, and

industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas include imports of ephedrine, pseudoephedrine, and phenylpropanolamine but do not include imports of controlled substances for use in industrial processes.

On July 17, 2015, a notice titled, “Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Proposed Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2016” was published in the *Federal Register*. 80 FR 42540. This notice proposed the 2016 aggregate production quotas for each basic class of controlled substance listed in schedules I and II and the 2016 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. All interested persons were invited to comment on or object to the proposed aggregate production quotas and the proposed assessment of annual needs on or before August 17, 2015.

### **Comments Received**

Twenty comments were received from four DEA-registered manufacturers within the published comment period regarding 17 different schedule I and II controlled substances. The DEA did not receive any comments regarding the proposed assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. Commenters stated that the proposed aggregate production quotas for [1-(5-fluoropentyl)-1*H*-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201), amphetamine (for sale), codeine (for sale), gamma hydroxybutric acid, levorphanol, marihuana, methylphenidate, *N*-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA), *N*-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-

fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA), *N*-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB-CHMINACA), *N*-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (AB-PINACA), *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide (acetyl fentanyl), nabilone, oxymorphone (for conversion), oxymorphone (for sale), Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-Flouro-PB-22), and Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22) were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks.

#### **Determination of 2016 Aggregate Production Quotas and Assessment of Annual Needs**

In determining the 2016 aggregate production quotas and assessment of annual needs, the DEA has taken into consideration the above comments along with the factors set forth at 21 CFR 1303.11 and 21 CFR 1315.11, in accordance with 21 U.S.C. 826(a), and other relevant factors, including the 2015 manufacturing quotas, current 2015 sales and inventories, anticipated 2016 export requirements, industrial use, additional applications for 2016 quotas, as well as information on research and product development requirements. Based on this information, the DEA has determined that adjustments to the proposed aggregate production quotas for codeine (for sale), hydromorphone, marihuana, methylphenidate, and *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide (acetyl fentanyl) are warranted. This final order reflects those adjustments.

Regarding [1-(5-fluoropentyl)-1*H*-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201), amphetamine (for sale), gamma hydroxybutric acid, levorphanol, *N*-(1-Amino-

3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA), *N*-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA), *N*-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB-CHMINACA), *N*-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (AB-PINACA), nabilone, oxymorphone (for conversion), oxymorphone (for sale), Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-Flouro-PB-22), and Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22), the DEA has determined that the proposed aggregate production quotas are sufficient to provide for the 2016 estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks. This final order establishes these aggregate production quotas at the same amounts as proposed.

As described in the previously published notice proposing the 2016 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. *See* 21 CFR 1303.24. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, the DEA has included in all established schedule II aggregate production quotas, and certain schedule I aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The established aggregate production quotas will

reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. The DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforeseen event results in the substantial disruption to the amount of controlled substances available to provide for legitimate public need, as determined by the DEA. The DEA does not anticipate utilizing the reserve in the absence of these circumstances.

In accordance with 21 U.S.C. 826, 21 CFR 1303.11, and 21 CFR 1315.11, the Administrator hereby establishes the 2016 aggregate production quotas for the following schedule I and II controlled substances and the 2016 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic Class	Established 2016 Quotas
	(g)
<b>Schedule I</b>	
(1-Pentyl-1 <i>H</i> -indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	25
[1-(5-fluoropentyl)-1 <i>H</i> -indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201)	15
[1-(5-Fluoro-pentyl)-1 <i>H</i> -indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	25
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	25
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	25
1-(1-Phenylcyclohexyl)pyrrolidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45

1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45
1-Methyl-4-phenyl-4-propionoxypiperidine	2
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30
2-(2,5-Dimethoxy-4- <i>n</i> -propylphenyl)ethanamine (2C-P)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30
2-(4-Bromo-2,5-dimethoxyphenyl)- <i>N</i> -(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	25
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)- <i>N</i> -(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	25
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)- <i>N</i> -(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	15
2-(Methylamino)-1-phenylpentan-1-one (pentedrone)	25
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4- <i>n</i> -propylthiophenethylamine	25
2,5-Dimethoxyamphetamine	25
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30
3,4,5-Trimethoxyamphetamine	25
3,4-Methylenedioxyamphetamine (MDA)	55
3,4-Methylenedioxy-methamphetamine (MDMA)	50
3,4-Methylenedioxy- <i>N</i> -ethylamphetamine (MDEA)	40
3,4-Methylenedioxy- <i>N</i> -methylcathinone (methylone)	50
3,4-Methylenedioxy-pyrovalerone (MDPV)	35
3-Fluoro- <i>N</i> -methylcathinone (3-FMC)	25

3-Methylfentanyl	2
3-Methylthiofentanyl	2
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25
4-Fluoro- <i>N</i> -methylcathinone (4-FMC)	25
4-Methoxyamphetamine	150
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl- <i>N</i> -ethylcathinone (4-MEC)	25
4-Methyl- <i>N</i> -methylcathinone (mephedrone)	45
4-Methyl- $\alpha$ -pyrrolidinopropiophenone (4-MePPP)	25
5-(1,1-Dimethylheptyl)-2-[(1 <i>R</i> ,3 <i>S</i> )-3-hydroxycyclohexyl]-phenol	68
5-(1,1-Dimethyloctyl)-2-[(1 <i>R</i> ,3 <i>S</i> )-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	53
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy- <i>N,N</i> -diisopropyltryptamine	25
5-Methoxy- <i>N,N</i> -dimethyltryptamine	25
Acetyl- <i>alpha</i> -methylfentanyl	2
Acetyldihydrocodeine	2
Acetylmethadol	2
Allylprodine	2
Alphacetylmethadol	2
<i>alpha</i> -Ethyltryptamine	25
Alphameprodine	2
Alphamethadol	2
<i>alpha</i> -Methylfentanyl	2
<i>alpha</i> -Methylthiofentanyl	2
<i>alpha</i> -Methyltryptamine (AMT)	25
<i>alpha</i> -Pyrrolidinobutiophenone ( $\alpha$ -PBP)	25
<i>alpha</i> -Pyrrolidinopentiophenone ( $\alpha$ -PVP)	25
Aminorex	25
Benzylmorphine	2
Betacetylmethadol	2
<i>beta</i> -Hydroxy-3-methylfentanyl	2
<i>beta</i> -Hydroxyfentanyl	2
Betameprodine	2



Betamethadol	4
Betaprodine	2
Bufotenine	3
Cathinone	70
Codeine methylbromide	5
Codeine- <i>N</i> -oxide	305
Desomorphine	25
Diethyltryptamine	25
Difenoxin	11,000
Dihydromorphine	3,000,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylamine	5
<i>gamma</i> -Hydroxybutyric acid	70,250,000
Heroin	50
Hydromorphenol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	40
Marihuana	658,000
Mescaline	25
Methaqualone	10
Methcathinone	25
Methyldesorphine	5
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine- <i>N</i> -oxide	350
<i>N</i> -(1-Adamantyl)-1-pentyl-1 <i>H</i> -indazole-3-carboxamide (AKB48)	25
<i>N</i> -(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1 <i>H</i> -indazole-3-carboxamide (ADB-PINACA)	50
<i>N</i> -(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1 <i>H</i> -indazole-3-carboxamide (AB-FUBINACA)	50
<i>N</i> -(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1 <i>H</i> -indazole-3-carboxamide (AB-CHMINACA)	15
<i>N</i> -(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1 <i>H</i> -indazole-3-carboxamide (AB-PINACA)	15
<i>N</i> -(1-phenethylpiperidin-4-yl)- <i>N</i> -phenylacetamide (acetyl fentanyl)	100

<i>N,N</i> -Dimethylamphetamine	25
Naphthylpyrovalerone (naphyrone)	25
<i>N</i> -Benzylpiperazine	25
<i>N</i> -Ethyl-1-phenylcyclohexylamine	5
<i>N</i> -Ethylamphetamine	24
<i>N</i> -Hydroxy-3,4-methylenedioxyamphetamine	24
Noracymethadol	2
Norlevorphanol	52
Normethadone	2
Normorphine	40
Para-fluorofentanyl	5
Parahexyl	5
Phenomorphane	2
Pholcodine	5
Psilocybin	30
Psilocyn	50
Quinolin-8-yl 1-(5-fluoropentyl)-1 <i>H</i> -indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	50
Quinolin-8-yl 1-pentyl-1 <i>H</i> -indole-3-carboxylate (PB-22; QUPIC)	50
Tetrahydrocannabinols	511,250
Thiofentanyl	2
Tilidine	25
Trimeperidine	2
<b>Schedule II</b>	
1-Phenylcyclohexylamine	5
1-Piperidinocyclohexanecarbonitrile	5
4-Anilino- <i>N</i> -phenethyl-4-piperidine (ANPP)	2,950,000
Alfentanil	17,750
Alphaprodine	3
Amobarbital	25,125
Amphetamine (for conversion)	15,000,000
Amphetamine (for sale)	39,705,000
Carfentanil	19
Cocaine	200,000
Codeine (for conversion)	50,000,000
Codeine (for sale)	63,900,000

Dextropropoxyphene	45
Dihydrocodeine	226,375
Dihydroetorphine	3
Diphenoxylate (for conversion)	31,250
Diphenoxylate (for sale)	1,337,500
Ecgonine	125,000
Ethylmorphine	3
Etorphine hydrochloride	3
Fentanyl	2,300,000
Glutethimide	3
Hydrocodone (for conversion)	235,000
Hydrocodone (for sale)	88,500,000
Hydromorphone	8,250,000
Isomethadone	5
Levo-alphaacetylmethadol (LAAM)	4
Levomethorphan	30
Levorphanol	7,125
Lisdexamfetamine	29,750,000
Meperidine	5,450,000
Meperidine Intermediate-A	6
Meperidine Intermediate-B	11
Meperidine Intermediate-C	6
Metazocine	19
Methadone (for sale)	31,875,000
Methadone Intermediate	34,375,000
Methamphetamine	2,061,375
[1,250,000 grams of <i>levo</i> -desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]	
Methylphenidate	96,750,000
Morphine (for conversion)	91,250,000
Morphine (for sale)	62,500,000
Nabilone	18,750
Noroxymorphone (for conversion)	17,500,000
Noroxymorphone (for sale)	1,475,000
Opium (powder)	112,500
Opium (tincture)	687,500

Oripavine	30,000,000
Oxycodone (for conversion)	6,250,000
Oxycodone (for sale)	139,150,000
Oxymorphone (for conversion)	29,000,000
Oxymorphone (for sale)	7,750,000
Pentobarbital	38,125,000
Phenazocine	6
Phencyclidine	50
Phenmetrazine	3
Phenylacetone	50
Racemethorphan	3
Racemorphan	3
Remifentanil	3,750
Secobarbital	215,003
Sufentanil	6,255
Tapentadol	25,500,000
Thebaine	125,000,000
<b>List I Chemicals</b>	
Ephedrine (for conversion)	100,000
Ephedrine (for sale)	4,000,000
Phenylpropanolamine (for conversion)	22,400,000
Phenylpropanolamine (for sale)	8,500,000
Pseudoephedrine (for conversion)	7,000
Pseudoephedrine (for sale)	224,500,000

The Administrator also establishes aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 at zero. In accordance with 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Administrator may adjust the 2016 aggregate production quotas and assessment of annual needs as needed.

Dated: September 30, 2015

Chuck Rosenberg,  
*Acting Administrator*

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